Delaware Health
And Social Services

DIVISION OF MANAGEMENT SERVICES

PROCUREMENT

DATE: October 08, 2008

PSC #826

CLINIC AND LONG TERM CARE FACILITY LABORATORY SERVICES

FOR

DIVISION OF PUBLIC HEALTH

Date Due: NOVEMBER 12, 2008
11:00 AM

ADDENDUM # 1 Please Note:

THE ATTACHED SHEETS HEREBY BECOME PART OF THE ABOVE MENTIONED BID.

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Request for Proposal No. PSCO-826
for
Clinic and Long Term Care Facility Laboratory Services

10/08/2008 Pre-Bid Meeting
Questions and Answers

1. Number of tests in 2007:
   - Unable to calculate the total Pap smears because of the terminology used in the calculations. Please clarify.
   - We calculated the number of tests as ThinPrep w/RFX HPV at 2508, Cyto ThinPrep Pap at 541 and Cyto GYN-1 at 99. These three together is what we consider as the total number of Pap smears. Am I right, or am I wrong?

See page 45 of the RFP. In 2007, the Division of Public Health (DPH) provided approximately 3,100 Pap smears.

   - Are there any conventional Pap smears?

Conventional smears were reported in 2007; however, the standard now for the State of Delaware is the ThinPrep Pap. There will be no conventional smears from this point forward.

   - Do the numbers used include all the insurances and the non-insurances?

Yes. Public Health's focus is on the uninsured and those individuals who are enrolled in Medicaid managed care. We are a gap service provider. DPH will provide the successful vendor with any information that we have for clients who have a third party insurer. At no time does the vendor bill the client. The vendor either bills Public Health or the insurer but never the clients.

2. Extension:
   - How much weight is given to quality assurance on the two-year extension?
   - Five years on the same terms seems highly unusual in healthcare when new tests and new technology is old news in two years. For instance, conventional Pap smears five years back were acceptable but in 2009, this would be close to being a rarity provided only by those who are determined not to change. Very similarly, 80% of our work comes with HPV testing even for those under 30 years of age and your contract still requires this for only those over 30 years of age.
   - How will changes in technology during the contract term change the extension and subsequent pricing?

Questions 2 & 3 are somewhat related and the following response applies to both questions.

See page 24. The terms of the contract regarding quality assurance would be consistent with those terms for a renewal. There are no extensions in our process. We do have

contract renewals after the first 36-month period. After the initial contract period of 36 months there is a possibility of renewal for up to two additional years with the successful vendor. Renewals are contingent upon the availability of funds. If DPH were to determine that we had a need to upgrade or revisit the services we were willing to reimburse, we would work with the contractor via the contract amendment process.

- ***Additional question: There is nothing else here that would add to the number of Pap smears?***

No. We are a gap service provider and we try to get our clients into their medical homes.

3. Technology change:
   - While HPV testing is available only on LBC, there are new technologies coming soon that can test P16 on a smear. How does the contract make accommodations for new technology that will benefit the clients and health care in the community, maybe at a minimally higher cost?

If DPH determines that a need exists, then we would work through the contract amendment process to determine whether this service would be offered and at what cost reimbursement would be made.

4. Number of tests:
   - Will reflex testing be considered an additional test?

Yes.

5. What is a control number? Can we create a medical record number?

The Delaware LIMs system generates a number and you can create a medical record number. You should be designing your system, or explain your current system, regarding how you would track our shared clients.

6. Will the vendor not bill the client, his/her portion of the deductible, co-pay etc… as required by law?

See page 12 of the RFP. For clients with third party insurance coverage, Public Health will provide the successful vendor with the necessary insurance information for billing. Again, the vendor does not bill the clients. The vendor either bills Public Health or the insurance company.

Additional Question: So we would be billing Public Health for the co-pay or deductible from the client's insurance?

The vendor will not bill Medicaid clients.

Additional Question: I bill Medicare 80% and by law the 20% has to be billed to the client.

That impacts Long Term Care (LTC) and not Public Health (PH) because PH clinics do not see clients in that age range. Long Term Care requires the vendor to bill the facility and provide detailed billing and payment information regarding the services rendered to

the resident. LTC facility staff researches sources of payment prior to submitting to their respective financial offices.

7. Reportable diseases:
   - Can this be done on a monthly basis or does it have to done immediately after detection? Currently the state has us reporting to them monthly on communicable diseases and cancers.

See page 12 of the RFP for the communicable disease reporting link. This RFP does not ask for any change in disease reporting requirements. Reportable disease reporting is different than providing test results. Please refer to the regulation for reportable disease procedures and to the RFP for when and how to communicate lab test results.

8. Why should the pathologists be a member of CAP as long as they are board certified and licensed and what accrediting bodies are there other than CAP that a pathologist can become member of?
   - In a large commercial lab, would you require every pathologist to be a member of CAP?

This requirement is listed under the Long Term Care component of the RFP.
The American Society of Clinical Pathologists also renders certifications. The CAP certifies the laboratory for which the doctor works. Per Long Term Care, pathologists must be board-certified and licensed.

9. Why is only Thin Prep allowed and not the other LBC; while the latter are not FDA approved for HPV, 28% of laboratory tests are not and these newer LBCs are cheaper and in some occasions better than Thin Prep? CLIA allows non-FDA approved tests as long as there is internal validation as per CLIA rules by the laboratory.

The standard in the Division of Public Health (DPH) is the ThinPrep. That decision is based on DPH program directors' input. We will use the FDA approved tests.

Additional Question: With other tests that you are asking us to do, like lead testing, many of the protocols are not FDA approved.

Relative to lead testing, the confirmatory testing is performed at the DE Public Health Lab.

10. What is an abnormal Pap test; ASCUS and above; do you want us to call every ASCUS on a conventional smear?

There will no longer be conventional smears.

   - How will this be documented?

See page 15 of the RFP regarding documentation of tests.

   - Who should call and who will be authorized to receive the phone results?

In Public Health the teleprinter process is in place and we will provide the appropriate contact information to the successful bidder at the time the contract is awarded. Long Term Care will also do the same thing, since those institutions operate on a 24/7 basis.

   - Why use the teleprinter to print this result when it is available on the Web, especially when reflex testing will be performed on the same specimen?

Teleprinters are our lifeline as well as our backup system in case LIMS or other systems are not operating. We stand by the requirement that teleprinters are necessary for our procedures.

- Would you prefer an addendum for the additional testing when Good Practices in Pathology recommends a single report?

We request preliminary reports and follow-up reports.

Additional Question: The RFP requires all abnormal Pap smears to be called. Is that a mistake or do you require calls for every ASCUS?

At this point, DPH clinics do not receive telephone calls for any abnormal Pap smears. Correction: vendor will not be required to call DPH for every ASCUS.

Additional Question: I would also ask you to note that you have no requirement for CBC or any other critical value to be called.

Long Term Care requires critical values be reported by telephone. These values include:

TEST	REFERENCE	LOW PANIC	HIGH PANIC
Calcium	8.5 – 10.6	7.0	13.0
Potassium	3.5 - 5.5	2.9	6.5
Sodium	135 - 148	124	160
Hematocrit	34% - 50%	24%	
Hemoglobin	11.5 – 17	7.9	
WBC	4K – 10.5K	1.0K	15.0K
Platelets	140K – 415K	30K	
Carbamazepine	4.0 – 12.0		20.0
Digoxin	0.9 – 2.0		2.5
Phenobarbital	15 - 40		60
Phenytoin	10.0 – 20.0		40.0
Valproate	50 - 120		150

11. What is CYTOPATH, GYN 1?

That is the conventional Pap smear and it should not have been included.

12. How uniformly can the TAT be counted at every site from specimen pick up; do you have a clock out?

Public Health staff log specimens that are sent out for testing on a daily basis in a manual system. Long Term Care also logs specimens sent out and requires the contractor to call critical values.

Additional Question: How do you judge proper turnaround time within a certain number of hours from pickup when you don't see the pickup?

Lab specimen pick-ups are to occur daily during business hours.

Additional Question: You would insist that whoever wins the contract pick up the specimens in front of you, before you close.

The successful bidder will pick-up specimens from the public health clinic field and stat lab refrigerators located within state service centers on or before 4:30 PM Monday

through Friday. Long Term Care also requires the contractor to obtain specimens from specific sites located within each facility.

Most laboratories leave a box outside.
You may add clarification in your proposals regarding anything you think is value-added regarding your services.

13. TB & Fungal cultures may take more than 80 hours for a final result. Is this flexible?
All TB specimens obtained in Public Health clinical settings are sent to the Delaware Public Health Lab. Public Health clinics are not primary providers and we do not obtain specimens to determine fungal cultures.

Additional Question: When you do a culture, you may not know the patient has TB. There are many times we have to hold a specimen for six to eight weeks. It could take much more than 80 hours.
Long Term Care is flexible regarding the 80 hour final result for Fungal or TB testing.

14. In this electronic age why insist on teleprinters and not just use DHIN? Teleprinters are expensive and require heavy maintenance. All the labs in the State are on DHIN. Most of our clients print their reports from the web access at DHIN. Having been in the Board of Medical Practice, printing your own reports is the safest and surest way. In addition, once there is EMR in the next year or so, reports will go directly into the system totally eliminating the need for any printing. This is the most cost effective and least liability for the lab and the provider.
    - Will the contract accommodate for this change?

To date the Public Health clinics have not converted to electronic medical records. Long Term Care can obtain results electronically through their current vendor site.
At the time this RFP was written, our administration gave us no indication that we would be going on-line within the next year. When Public Health agrees a change should be made, we would work with the successful vendor and decide what accommodations would be made.

15. How do you calculate lost specimens, delayed pick up, calling of critical values etc.?
To my colleagues' knowledge, lost specimens are not an issue. We would recognize delayed pick up as acceptable if there were severe adverse weather conditions or we were actually in a state of emergency declared by the governor. Calling of critical values is good lab practice. This issue is more appropriate for the Long Term Care component of the RFP vs. the clients on the Public Health side. DPH welcomes any additional information and value-added services related to quality assurance vendors wish to provide in their applications.

16. Since human errors cannot be totally avoided, will having a policy for Early Detection of Errors and documentation of a close review by the Medical Director be viewed as a favorable process in case of errors?

Please provide us with any services you think will add value to the proposal.

17. The contract says 10-day turnaround time for Pap smears, but one day for CBCs. Is this correct, that this is acceptable even when there is cancer in the Pap?

The typical turnaround is 3-4 days with a maximum of 7 days. The 10-day turnaround accounts for follow up testing and the final report. DPH welcomes calls and the additional contact if it is a critical area. Good lab practice in calling in critical values is welcomed. This response is also related to Question 24.

18. Do not see the QA statistics mentioned in detail for Pap Smears as indicated for other tests. For instance, would vendors be required to say what percentage of their abnormal Paps had matching abnormal biopsies; i.e., what percentage of HSIL or cancer have to be CIN 2-3 or cancer on the biopsy? Can all ASCUS be CIN 3 on a biopsy? I am concerned that just requiring only CLIA compliance is very subjective, depending on the whims of the inspector. Will the State work with the vendors to make things more specific like we all do in our regular practice?

CLIA compliance is expected. Please provide us with any services you think will add value to the proposal.

Additional Comment: The reason I am mentioning this is you have required voluminous data for epidemiology.

The program directors represented here today have grant requirements and we also use these data for planning and evaluation. These data are necessary. Please provide us with any services you think will add value to the proposal.

19. Given that the proposal is giving consideration to State references for entities that have held previous State contracts, why is no consideration being given to references for entities that have not previously held State contracts?

The Division of Health and Social Services and DPH require all of your state contract information to be reported and a minimum of three non-state references. You may provide as many non-state references as you wish. That requirement is standard Department RFP boilerplate language and is not unique to this RFP.

20. Given that Clinical Pathology (CP) and Anatomical Pathology (AP) are two distinct fields requiring separate training and board examinations and having significantly different liability risks, why are they being combined in this proposal?

That is the choice of the Division. It is not an option for us to separate them. This procedure works for the Division and we have not had a problem with it in the past. It was the decision of the Division to move forward in the same manner by combining the CP and AP.

21. What, if any, cost benefit is achieved by combining CP and AP in the same proposal?

That is the choice of the Division. It is a better option for us, that is the way the RFP was written, and that is what everybody should be preparing their bid to reflect.

22. If any cost benefit is achieved by combining CP and AP, what is the basis and source for such cost benefit and what alternatives, if any were considered or evaluated?

See the answer to Question 21 above. That is the choice of the Division.

23. How does the combination of CP and AP in one proposal serve your stated goals of providing positive health for Delaware residents and to provide timely, accurate and reliable test results?

DPH has a track record of success and we are going to continue with the combination of CP and AP.

24. Why is there a lengthy ten (10) day period to allow for the return of PAP results when local entities can provide PAP results in significantly less time?

This question is related to Question 17. The 10-day period includes any and all follow-up testing reports.

25. What is the purpose of the Epidemiology data required in the contract? Why is quality assurance data, such as mistakes in diagnosis, previous lawsuits regarding patient care, etc... excluded from the consideration?

See the answer to Question 18 regarding the needs of our program managers for grant requirements as well as for planning and evaluation purposes.

Note to Bidders: The Division of Public Health (DPH) did not give permission to any bidder to contact any DPH staff, other than those stated in the RFP, concerning any past, current, or future services related to this RFP. Any information obtained from any such contact shall not be used in the preparation of a response to this RFP.